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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/522,554	03/10/2000	Francis M. Rossi	16650016US01	5524

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EXAMINER

CEPERLEY, MARY

ART UNIT

PAPER NUMBER

1641

13

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/522,554

Applicant(s)

ROSSI, FRANCIS M.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 13, 15-17, 19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13, 15-17, 19, and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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**1)** Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

**2)** The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**3)** The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**4)** Claims 13, 15-17, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**a)** In claim 13, it is unclear where the "plurality of molecules of interest" of (b) are physically positioned relative to the "electrode array device" of (a). The limitation that the "plurality of molecules of interest" "**bind to** complementary affinity anchor molecule oligonucleotides" does not limit the positioning of the "plurality of molecules of interest" since the claim language does not require that these molecules be **actually bound** to the oligonucleotides.

**b)** In claim 13, subparagraph (b), it is totally unclear how the "**binding entity**" is physically related or attached to the "oligonucleotide moiety".

**5)** Claims 13, 15-17, 19 and 20 are rejected under 35 USC 112, first paragraph, as not corresponding to the enabling written description of the invention as it is set forth in the specification.

**a)** The claim limitation of paragraph (b) of claim 13 that the "plurality of molecules of interest" are comprised of "oligonucleotides" and "**a binding entity selected from the group consisting of peptides, antibodies, and combinations thereof**" is not supported by an enabling written

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description in the specification of such a combination. At page 8 of the November 29, 2002 response (Advisory Action Item 5) applicant argues that this claimed combination patentably defines over the invention of Montgomery but does not describe where this combination finds enablement in the specification. Page 19, line 36 – page 20, line 7 of the specification describes the **direct** binding of the “affinity anchor” to its complementary specific binding pair member, e.g. an oligonucleotide hybridizing with another oligonucleotide, but does not address the presence of any other “binding entity” on the “molecule of interest”. It is not clear how the invention would operate when the “molecule of interest” contains “oligonucleotides”, as claimed, in combination with “peptides, antibodies, and combinations thereof”. Since presumably the “peptides, antibodies, and combinations thereof” contain the moieties that would specifically bind to other peptides or antigens, the function of the “oligonucleotides” is unclear.

In the November 29, 2002 response, at page 3, the second subparagraph of paragraph a., applicant states that

“...claim 13 requires merely a self assembly of different molecules of interest wherein each molecule of interest has an oligonucleotide moiety that hybridizes to the corresponding first oligonucleotide in the porous reaction layer.”

Nothing is said about the presence or function of the required “peptides, antibodies, and combinations thereof” recited in claim 13. See also, applicant’s statement in the last paragraph of page 6, of the November 29, 2002 response wherein applicant intends “to only provide for **hybridization** of complementary **oligonucleotides** moieties”. What is the function of the required “peptides, antibodies, and combinations thereof” in the “hybridization”?

Applicant’s statement made in the last two lines of page 8 of the November 29, 2002 response is not understood, namely, that “claim 17 is not a hybridization of an oligonucleotide target to an electrode array”. In clear distinction with this statement, claim 17, step (b) **specifically requires** that the “molecule of interest” contain “an oligonucleotide moiety that **hybridizes to a complementary affinity anchor molecule**” and step (c) requires that the “molecules of interest localize to known locations by

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binding the affinity anchor molecule **to the complementary oligonucleotide moiety of the molecule of interest**".

**b)** There is no enabling written description in the specification for the limitation that the "the plurality of affinity anchor molecules (i.e. "oligonucleotides") are located **within** the porous matrix". The specification, at page 6, lines 11-13 describes "electrochemically immobilizing a well-defined array of affinity anchors **onto** a porous membrane". Page 5, lines 9-12 of the specification describes a biotin/streptavidin "anchor spot immobilized in the membrane", but not "oligonucleotides" so immobilized.

**6)** The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**7)** Claims 13, 15-17, 19, and 20 are rejected under 35 U.S.C. 102(b)/(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over each of Montgomery (U.S. 6,280,595), Ackley et al (U.S. 6,254,827), Heller et al (U.S. 5,632,957), Ribí et al (U.S. 5,571,568), or Hafeman et al (U.S. 4,591,550) for the reasons set forth in paragraph 8. of the October 03, 2001 first Office action and as further discussed in the final rejection and advisory Office actions.

Applicant's arguments filed November 29, 2002 have been fully considered but they are not persuasive. In order to further prosecution, applicant needs to discuss on the record the "hybridization" problem described in paragraphs **4)** and **5)** above, i.e. whether or not a "hybridization" is intended between the "affinity anchor" defined as a "oligonucleotide" and the "oligonucleotide moiety" of the "molecule of interest" and what purpose the "peptides, antibodies, and combinations thereof" serve. After the exact nature of the invention (i.e. the specific type of bonding involved) is clarified, the examiner will be in a position to more fully compare the actual claimed invention with the cited prior art. Upon this clarification, the examiner will again reconsider the characterizations of the prior art references and arguments presented in applicant's November 29, 2002 response. Applicant is also encouraged to consider what is actually required by the claim language of claims 13 and 17 with regard to the minimum

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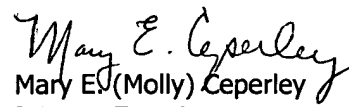
recited components of the "device" and the configuration of these components vis a vis the descriptions of the prior art. It is noted that, in the absence evidence of criticality, equivalent conventional specific binding member pairs would be considered to be obvious over each other, i.e. the description of the immobilization of an antigen by binding to its corresponding immobilized antibody would be considered to be equivalent to and would render obvious the binding of an oligonucleotide to its complementary oligonucleotide (members of another well known specific binding pair).

**8)** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE** at **(703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

February 19, 2003

  
Mary E. (Molly) Ceperley  
Primary Examiner  
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